APR 2 9 2011

# 510(k) Summary

## Pioneer Surgical Technology
## Special 510(k): Device Modification

## FortrOss Bone Void Filler

### ADMINISTRATIVE INFORMATION

Manufacturer Name:
Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855
Telephone: +1 (906) 226-4812
Fax: +1 (906) 226-4459

Official Contact:
Jonathan Gilbert

Representative/Consultant:
David J. Collette, MD or
Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: +1 (858) 792-1235
Fax: +1 (858) 792-1236
Email: dcollette@paxmed.com
flarson@paxmed.com

### DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Proprietary Name: | FortrOss Bone Void Filler |
| Common Name: | Bone Void Filler |
| Classification Regulations: | Filler, Bone Void, Calcium Compound<br>21 CFR 888.3045, Class II |
| Product Code: | MQV |
| Classification Panel: | Orthopaedic and Rehabilitation Devices |
| Reviewing Branch: | Restorative Devices Branch |

## INTENDED USE

*FortrOss Bone Void Filler* is indicated for bony voids or gaps that are not intrinsic to the stability of bony structure. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product is indicated to be used in the posterolateral spine in conjunction with bone marrow aspirate and autograft bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

## DEVICE DESCRIPTION

FortrOss Bone Void Filler is a resorbable bone void filler consisting of calcium phosphate in a porcine gelatin carrier provided in granular form. FortrOss Bone Void Filler is radiopaque, provided sterile and is intended for single use only.

## PREDICATE DEVICE

K091031 – Pioneer FortrOss Bone Void Filler

## COMPARISON TO MARKETED DEVICE

The intended use and composition of this device are identical to those of the predicate. This submission introduces a larger (20 cc) product size, a packaging modification consisting of a mixing chamber intended to facilitate reconstitution of the device at the time of implantation, and an accessory to facilitate placement of the device along the posterolateral spine.

## PERFORMANCE TESTING

Non-clinical evaluation consisting of material specifications and engineering design review and validation relevant to the line extensions described above were performed.

## CONCLUSION

Based on information presented in this submission, we conclude that the FortrOss Bone Void Filler is substantially equivalent to predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 2 9 2011

Pioneer Surgical Technology
% PaxMed international, LLC
David J. Collette, M.D.
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K110561
Trade/Device Name: FortrOss Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: March 31, 2011
Received: April 1, 2011

Dear Dr. Collette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number: K110561

Device Name: FortrOss Bone Void Filler

Indications for Use

*FortrOss Bone Void Filler* is indicated for bony voids or gaps that are not intrinsic to the stability of bony structure. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product is indicated to be used in the posterolateral spine in conjunction with bone marrow aspirate and autograft bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110561